

FORM PTO-1390 (Modified)  
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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

UAB-15602/22

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5)

10/019873

INTERNATIONAL APPLICATION NO  
PCT/US00/08695INTERNATIONAL FILING DATE  
30 March 2000PRIORITY DATE CLAIMED  
30 March 1999

TITLE OF INVENTION

METHOD AND APPARATUS FOR PASSIVE CARDIAC STIMULATION

APPLICANT(S) FOR DO/EO/US

IDEKER, Raymond E. and GIROUARD, Steven D.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau)
  - b. ☐ has been communicated by the International Bureau.
  - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4)
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired
  - d. ☒ have not been made and will not be made
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3))
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5))
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

## Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4)
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information

postcard



25006

PATENT TRADEMARK OFFICE

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/019873		PCT/US00/08695		UAB-15602/22	
24. The following fees are submitted:				CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE ( 37 CFR 1.492 (a) (1) - (5)) :					
<input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO . . . . .				\$1040.00	
<input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO . . . . .				\$890.00	
<input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO . . . . .				\$740.00	
<input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) . . . . .				\$710.00	
<input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) . . . . .				\$100.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$100.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				\$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	44 - 20 =	24	x \$18 00	\$432.00	
Independent claims	4 - 3 =	1	x \$84 00	\$84.00	
Multiple Dependent Claims (check if applicable).			<input type="checkbox"/>	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$746.00	
<input checked="" type="checkbox"/> Applicant claims small entity status See 37 CFR 1.27). The fees indicated above are reduced by 1/2				\$373.00	
SUBTOTAL =				\$373.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f))				\$0.00	
TOTAL NATIONAL FEE =				\$373.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).			<input type="checkbox"/>	\$0.00	
TOTAL FEES ENCLOSED =				\$373.00	
				Amount to be: refunded	\$
				charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$373.00 to cover the above fees is enclosed					
b. <input type="checkbox"/> Please charge my Deposit Account No _____ in the amount of _____ to cover the above fees A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No 07-1180 A duplicate copy of this sheet is enclosed.					
d. <input type="checkbox"/> Fees are to be charged to a credit card WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO.					
Ellen S. Cogen Gifford, Krass, Groh, Sprinkle, Anderson & Citkowski, P.C. 280 N. Old Woodward Avenue, Suite 400 Birmingham, MI 48009-5394 (248) 647-6000					
SIGNATURE Ellen S. Cogen NAME 38,109 REGISTRATION NUMBER 10/25/01 DATE					

**METHOD AND APPARATUS  
FOR PASSIVE CARDIAC STIMULATION**

**Technical Field**

The subject invention relates to a method and apparatus for cardiac  
5 stimulation. In particular, the subject invention provides a passive conductor  
for use in combination with an implanted stimulating device for passively  
stimulating remote regions of the heart and a method of using same.

**Background of the Invention**

By way of background, the application of electrical current to the heart  
10 through electrodes either applied directly to the chest or through an implanted  
device is well known in the art. Typical implanted devices include  
defibrillators and/or pacemakers. These types of devices are usually surgically  
implanted into a subject and an intracavitary electrode is placed within or  
adjacent to the heart, typically transvenously.

15 While these implanted stimulating devices competently carry out their  
design task, there are many instances in which it would be desirable to  
electrically stimulate a portion of the heart that is either difficult to reach with a  
transvenously disposed electrode or which has been previously connected to an  
implanted electrode. For example, locations such as, but not limited to, the left  
20 ventricular apex, the anterior-basal left ventricular free wall, and the left atrium  
near the pulmonary veins. It may be necessary and advantageous to electrically  
stimulate the heart from these regions for reasons including multi-site pacing  
for congestive heart failure, single or multi-site pacing to prevent a ventricular  
or atrial tachyarrhythmia, single or multi-site pacing very soon after the onset of

an arrhythmia to halt the arrhythmia before it degenerates into ventricular or atrial fibrillation requiring a defibrillation shock, and multi-site electrodes for delivery of shocks with a lower defibrillation threshold than shocks delivered only through transvenous electrodes.

5           While electrodes on catheters inserted into veins of the heart by way of the coronary sinus can be placed in many cardiac locations, there are a number of spots or locations to which they cannot reach or be placed. Electrodes can be placed in almost any desired epicardial location during open-heart surgery. However, such surgery is expensive and is associated with both mortality and  
10 morbidity of the subject. With the advent of thoracoscopic surgery, it is now possible to implant such electrodes in the pericardial space by a much more minor procedure that requires only one or two small incisions for the insertion of a thoracoscopic device. However, this type of procedure is still complicated by the fact that the electrodes still must be connected to wires that are tunneled  
15 through the body to the pacemaker or defibrillator.

          It has been recognized that the heart is under profound control of the autonomic nervous system. There are many instances when electrical stimulation of the neural input to the heart could be beneficial for the alteration of cardiac electrophysiologic status. The difficulty in implementing neural  
20 stimulation of the heart has been in the development of an apparatus for the direct stimulation or inhibition of cardiac sympathetic and parasympathetic nerves.

Accordingly, it would be advantageous and desirable to have an apparatus and method for stimulating portions of the heart which are difficult or impossible to reach or stimulate with a transvenous electrode but which are accessible utilizing the less invasive thoracoscopic surgical technique and which is able to stimulate the remote regions of the heart without the necessity for tunneling wires through a body of the subject and connection to a pacemaker or defibrillator for a source of electrical stimuli.

Furthermore, it would also be advantageous and desirable to have a method and apparatus which allows for the selective stimulation of the heart.

10

#### **Summary of the Invention**

A passive conductor assembly for use with an implanted stimulating device having an intracavitarily or transvenously disposed electrode is disclosed. The passive conductor assembly for use in combination with the implanted stimulus generator having an intracavitarily or intravenously disposed electrode includes at least one conductive element having a first end and a second end, and/or other contact sites for contacting a desired or selected portion of a heart of a subject to be stimulated. The passive conductor assembly is disposed in proximity to the intracavitarily or transvenous electrode which is connected to the implanted stimulus generator such as a pacemaker or defibrillator. Upon discharge of an electrical stimulus or waveform from the implanted stimulus generator, the stimulus is conducted through the myocardial tissue to the conductor where it is passively conducted to a region of the heart in contact with an end or other contact sites of the

15  
20

conductive element of the passive conductor assembly which have been selected for cardiac stimulation.

The passive conductor assembly can include electrical components disposed in electrical communication therewith to provide for the manipulation and/or modification of the electrical stimulus or waveform generated by the implanted stimulus generator which can be designed, for example, to selectively stimulate only neural tissue and not cardiac tissue or vice versa through the same passive conductor assembly.

#### **Brief Description of the Drawings**

The following detailed description is best understood with reference to the following drawings in which:

Figure 1 illustrates the potential field from a 500-V 6ms unsuccessful defibrillation shock. The top two panels represent the subepicardial potentials, and the bottom two panels represent the subendocardial potentials. All panels show the potentials superimposed on the epicardial surface of the heart. The two panels on the left represent the left antero-lateral view of the heart, whereas the two panels on the right represent the right postero-lateral view of the heart. Numbers denote the location of the recording electrodes and the potential in volts recorded at each site. Isopotential lines are separated by 25V. Solid circles represent locations where good recordings were not obtained. The dashed line indicates the upper border of the right ventricular outflow tract. *LV* = left ventricle; *RV* = right ventricle; *RVOT* = right ventricular outflow

tract; *LAD* = left anterior descending coronary artery; *RCA* = right coronary artery; *Cx* = circumflex coronary artery.

### **Detailed Description of the Invention**

The present invention provides for a passive conductor assembly used  
5 in combination with an implanted cardiac stimulation device or generator such as a pacemaker or a defibrillator having an intracavitarily or intravenously disposed electrode. The passive conductor assembly can be placed by surgery or thoracoscopy to electrically stimulate the heart of a subject which does not require the running or tunneling of wires from the passive conductor assembly  
10 to the implanted stimulus generator. That is, the passive conductor assembly can be completely self-contained or disposed completely within the pericardial space of the heart and used in conjunction with a defibrillator or a pacemaker connected to leads or electrodes that are inserted into the heart.

The passive conductor assembly includes at least one conductive  
15 element having a first end, a second end, and/or other contact sites for contacting a portion of the heart of the subject. The conductive element is preferably comprised of a low-resistance material and can have any suitable length but typically ranges from approximately 1 cm to approximately 12 cm. The conductive element can be made of any conductive material but is  
20 preferably constructed of a metallic material in the form of wire or strips that are placed in the pericardial space and contact the heart. Additionally, the conductive element can be constructed of a composite ribbon of conductive material. The conductive elements can be exposed to the heart along their

entire length forming a single electrode, however, in a preferred embodiment, the conductive element is insulated along most of its length except at the two ends or other intermediate sites which form the electrodes or contact sites.

The insulator can comprise any suitable electrically insulative material that is also biocompatible. In a further embodiment, the insulation can be removed at one or more additional locations along the conductive elements to stimulate additional sites of the heart.

The ends of the conductive element should be placed at the points on the heart at which the electrical stimulus or waveform delivered by the pacemaker or the defibrillator, through their own transvenous electrode, creates a potential differential on the surface of the heart to facilitate the flow of the electrical stimulus. That is, if the two ends of the conductive element are placed at sites that have approximately the same electrical potential, little or no current will flow therethrough.

The exposed portions (ends and/or regions therebetween) of the conductive element in the contact with the heart can vary in size depending on the current density and the potential gradient in the immediately adjacent tissue. Typically, the contact portion of the conductive element can range from approximately 0.2 mm to 4 cm.

In order to modify the electrical stimulus or waveform received from the implanted stimulus generator, electrical components can be disposed in electrical communication with or along the conductive element. These electrical components can include, for example, diodes, devices capable of



storing energy such as capacitors, microprocessors, resistors, and the like. The electrical components can also be used in combinations such that the passive conductor can act as a low-pass or high-pass filter to modify the input stimulus or waveform from the implanted stimulus generator. In another embodiment, a diode could be placed along the conductive element such that the stimulus or electrical current could only flow in one direction along the conductive element during the stimulation. This embodiment has several advantages, for example, it becomes possible to pace from some sites in the heart but not others by controlling which polarity of stimulus was generated by the implanted stimulus generator through its electrode(s). If two or more conductors are utilized, then the diode could be oriented in one direction for some of the electrodes and oriented in the opposite direction for other of the electrodes so that the first set of electrodes would pass current with one polarity while the other set would pass current of the other polarity. An additional set of conductors could contain no diode such that they would pass current with either polarity. The use of electrical components disposed along the conductive element increases the flexibility of stimulating of myocardium in different combinations and in different sequences.

Diodes may also be useful for delivering defibrillation and cardioversion shocks. A concern when delivering a shock through two or more electrodes that are of the same polarity and the same or nearly same strength, is that a region of little current flow and potential gradient will be created on the heart at the point somewhere between the common polarity electrodes.

Creation of this low field region could significantly increase the defibrillation and cardioversion thresholds. Currently, most defibrillation shocks are biphasic with a second phase opposite in polarity to the first phase. The presence of the diode in one or more of the conductive elements would allow  
5 current to flow during one phase but not the other phase of the biphasic waveform. Therefore, the region of low field strength would only be present during one of the two phases of the shock so that the area could receive a stronger defibrillating field strength during the other phase.

In a further embodiment designed to avoid the region of low field  
10 strength throughout all phases of the shock, a capacitor is utilized instead of a diode along the length of the conductive element. The capacitor would allow current to flow during the early portion of the shock pulse thereby creating the low field strength region, but would not allow much current to flow later during the pulse, at which time the low field strength region would no longer  
15 be of the same strength and location. Towards the end of the shock pulse and after the shock pulse, the capacitor would discharge, creating a biphasic shock effect in some portions of the heart. If the shock pulse delivered from the defibrillator is, itself, biphasic, the second phase could be delivered either immediately after the first phase or after an interval of up to 5 ms or more since  
20 it has been shown that such a separation does not significantly decrease the beneficial effects of a biphasic pulse on defibrillation. Cooper et al. *Pace*, 16:471-482 (1993). Thus, with a short interval between the two phases of the shock, the capacitor would discharge during the second phase either partially or

entirely followed by charging in the opposite polarity toward the end of the second phase. This interaction would change the ratio of the currents passing through the passive conductor assembly and through the active intravascular defibrillation electrodes throughout the pulses. Accordingly, the size and  
5 location of the low field regions should change throughout the pulses instead being fixed in one region. The movement of this low field strength region should have a beneficial effect on the defibrillation threshold.

Alternatively, the two active phases of the shock could be separated by up to 5 or more ms so that the capacitor will largely discharge between the two  
10 phases and following the second active phase.

Biphasic pulses are frequently used for pacing to prevent electrolysis and the plating or the unplating of the pacing electrodes that can occur with a single polarity pulse. Disposing a capacitor along the length of the conductor would generate a biphasic pacing pulse since it allows only a zero net charge to  
15 pass through the conductor after it has been discharged.

Other electronic components used in combination with the passive conductor assembly could be useful. These components could be powered by the current that passes through the conductive element when a stimulus is delivered through the active intravascular electrodes of the pacemaker or  
20 defibrillator. Electronic components could store the charge to power the other components disposed along the conductive element for some period of time following pulses delivered by the pacemaker or the defibrillator. The pulses to charge these electronic components could either be delivered whenever needed

to treat or prevent arrhythmias or the pacemaker or defibrillator could deliver a small stimulus at specific time intervals for the sole purpose of charging the components disposed along the conductive element. This small stimulus could be of a frequency that does not stimulate the myocardium.

5           The electronic components that are powered along the conductive elements could perform several functions, for example, sensing activations at the ends or contacts on the conductive element. Pacing stimuli or shocks at these points along the conductive element could be time-based on the recorded activations from these electrodes. The timing algorithms could be performed  
10       by the electronic components disposed along the conductive element. Alternatively, the power in the conductive element could be used to pass a signal to the pacemaker or the defibrillator or its recording electrodes so that the software within the pacemaker or the defibrillator could control and integrate the responses of all of the passive conductors. Communication  
15       signals between the components disposed along the conductive element of the passive conductor and the pacemaker or the defibrillator could be by any modality including electrical or optical. If electrical, the frequency and strength of the signal could be such that the signal does not cause stimulation of the heart.

20           The passive conductor assembly is preferably oriented so that, during an electrical pulse delivered by the separated implanted stimulus generator, a potential difference is generated between the ends or other exposed regions (electrodes) of the conductive element disposed in the pericardial space.

Typically, at least one of the electrodes will be placed on the epicardium overlying one of the implanted stimulus generator leads or electrodes located within the cavities of the heart or veins. However, other orientations may also be useful. For example, as reported in a study by Callihan et al., (*JACC*, 1995; 25:1373-1379), it was found that a passive patch electrode located distant from the defibrillation electrodes of an implanted cardioverter/defibrillator would transfer most of the potential gradient that would normally be present beneath this electrode to concentrate it at the edges of the electrode. For a small electrical stimulus, this effect may make it possible to pace from the edge of the electrode with an electrical stimulus that would not be strong enough to pace this region in the absence of the passive conductor.

As stated above, the present invention provides a method and device for the stimulation or the inhibition of neural inputs to the heart with the purpose of preventing atrial or ventricular arrhythmias, terminating atrial or ventricular arrhythmias, assisting in atrial or ventricular defibrillation, control of heart-rate variability, or the improvement of cardiac function. By adding the passive electrical components to the passive conductive element and modulating the frequency of stimulation of the intracavitary electrode therewith, the present invention allows for selective stimulation and/or inhibition of neural tissue and not cardiac tissue or vice versa through the same passive conductor assembly.

The device for the extra-cardiac stimulation or inhibition of neural inputs to the heart is similar if not identical to the device described immediately above. The uninsulated portions (electrodes) of at least one conductive

element are disposed in contact with the heart and/or other tissues such as neural tissue, fat pads containing post-ganglionic neural fibers, cardiac veins adjacent to neural fibers, or other electrically excitable tissues such as the stellate ganglia and the vagus. The conductive element can also run  
5 circumferentially along the atrial-ventricular groove of the heart such that the sympathetic and the parasympathetic innervation, running parallel to cardiac vasculature, can be directly stimulated or inhibited. Typically, the electrical stimulation or inhibition will be achieved with the application of stimuli from approximately 1 to 20 mA at a frequency of approximately 1 to 50Hz. For  
10 neural stimulation, the stimulus could have a pulse width from approximately 10-250  $\mu$ sec, a current of approximately 1-20 mA, and a frequency of approximately 1-50Hz. For cardiac stimulation, the stimulus could have a pulse width from approximately 0.5-2 msec, a current of approximately 1-20 mA and a frequency of approximately 1-5Hz.

15 The conductive element should be oriented such that when an electrical stimulus or pulse is delivered from the implanted stimulus generator, an electrical potential difference will be created on the epicardial surface between the two or more exposed electrodes on the conductive element. As a result of this potential difference, current will be induced to flow in the conductive  
20 element. To achieve a sufficient potential difference in the passive conductor assembly, at least one conductive element should be placed in close proximity to the cardiac tissue overlying either an intracavitary electrode in an atrial or ventricular chamber, cardiac vein, or other location in or near the heart.

Alternatively, the passive conductor assembly having at least one conductive element may be placed in the pericardial space, an extra-pericardial space, or in other extra-cardiac locations. The passive conductor assembly can be placed during surgery that exposes these locations directly or may be placed  
5 using minimally invasive techniques such as thoracoscopic surgery, or transvenously through an introducing catheter. Additionally, passive conductor assemblies for both neural stimulation/inhibition can be combined with passive conductor assemblies for directly exciting cardiac tissue.

The largest effect utilizing the passive conductor assembly of the  
10 present invention is generally seen when one end of the conductive element is placed directly on the epicardium over the intravenous electrode of the stimulus generating device. However, this does not have to be the case. In order to refine the placement of the passive conductor assembly, it may be helpful to map the regions of the heart that depolarize and hyperpolarize in the absence of  
15 the passive conductor assembly during a stimulus passed through the intravenous electrode. The implanted stimulus generator should cause hyperpolarization at one end and depolarization at the other. Accordingly, it should be possible to place the passive conductor assembly in a region that is normally undergoing depolarization induced by the stimulus. These two  
20 effects should be additive so that the amount of stimulus needed to directly stimulate the particular region or area of the heart should be lower than when the end of the conductive element that causes depolarization is placed in a region that is undergoing hyperpolarization caused by the electrical stimulus

through the transvenously disposed electrodes. It is also possible that a similar beneficial effect might be seen if the end of the conductive element that causes hyperpolarization is placed in a region that is already undergoing hyperpolarization during the electrical stimulus.

5           As is stated above, more than one passive conductor assembly can be used in the same subject. For example, arrhythmias may be prevented by simultaneously stimulating from several sites on the heart. Two, three, or even more of the passive conductor assemblies could be placed in the pericardial space to pace from all of the sites. Even though the stimulus strength will be  
10       larger than if it was directly paced at each of the sites with electrodes connected directly to the implanted stimulus generator, the strength of the electrical stimulus should still be smaller than that required to directly activate all of these regions by a stimulus from the transvenous electrodes in the absence of the passive conductors of the present invention.

15           The passive conductor assembly of the present invention can be used for prevention and treatment of atrial-arrhythmias, ventricular arrhythmias, as well as for the control of cardiac performance through control of heart rate and atrial and ventricular refractory periods. Additionally, the passive conductor assembly can be used for the control of heart rate through stimulation of neural  
20       inputs to the sino-atrial and atrial-ventricular nodes of the heart.

Use of the passive conductor assembly of the present invention may be useful for augmenting traditional therapies such as antitachycardia pacing by altering the excitable gap through neural stimulation, thus improving the





wire was attached to the epicardium at these spots, current should flow through the wire and the potential gradient should be increased in the lateral-apical left ventricle. This should allow stimulation of the tissue in the lateral-apical left ventricle region with a much weaker stimulus than required in the absence of the wire.

For example, in the preferred embodiment of the invention an electric wire 100 has one end 102 both electrically and mechanically attached to a preselected region 104 of the heart, e.g. by suturing. A second end 106 of the wire 100 is both electrically and mechanically connected to a different region 108 of the heart, also preferably by suturing. Since the heart regions 104 and 108 of the heart attain different electric potentials during cardiac contraction, current flows through the wire thus achieving passive stimulation of the myocardium.

The wire 100 is electrically insulated in any conventional fashion between its ends 102 and 106. However, one or more points of the wire 100 between its ends may be electrically connected to the heart to provide passive stimulation during cardiac contraction.

As another example, the area near the pulmonary veins appears to frequently play a role in the induction and/or maintenance of atrial fibrillation. This is also the region in which the effect of the shock is weakest for electrodes in the right atrium and the distal coronary sinus as shown by Cooper et al. (Herzschr Elektrophys, 1998; 9:1-7). It should be possible to run a conductor to this region by way of the transverse sinus in the pericardial space. Such an

electrode location should be beneficial for pacing to prevent atrial fibrillation, for giving a small pacing or shocking stimulus or stimuli just as atrial fibrillation begins, or for giving a defibrillation shock to halt atrial fibrillation once it is established.

5           Other descriptive and exemplary materials are provided in Appendix A herewith.

          In view of the teaching presented herein, other modifications and variations of the present inventions will be readily apparent to those of skill in the art. The foregoing drawings, discussion, and description are illustrative of  
10       some embodiments of the present invention, but are not meant to be limitations on the practice thereof. It is the following claims, including all equivalents, which define the scope of the invention.

          Any patents or publications mentioned in this specification are indicative of the levels of those skilled in the art to which the invention  
15       pertains. These patents and publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

Claims

What is claimed:

- 1           1.     A method of electrically stimulating selected regions of a  
2     subject's heart having an implanted stimulus generator having an intracavitarily  
3     disposed electrode disposed in the subject, said method comprising the steps  
4     of:  
5           inserting into the subject at least one conductor having at least two  
6     electrical contacts thereon;  
7           contacting a portion of the heart to be stimulated with the electrical  
8     contact of the conductor;  
9           positioning the electrical contact of the conductor in contact with  
10    myocardial tissue such that an electrical stimulus delivered by the implanted  
11    stimulus generator creates an electrical potential difference at each contact of  
12    the conductor;  
13          generating a stimulus from the implanted stimulus generator; and  
14          discharging the electrical stimulus from the intracavitarily disposed  
15    electrode wherein the stimulus is conducted through the myocardial tissue and  
16    through at least one electrical conductor and is transferred to the regions of the  
17    heart contacting the electrical contacts of the conductor, whereby the current is  
18    sufficient to stimulate tissue of the heart.
- 1           2.     A method according to claim 1, wherein said inserting step  
2     further comprises surgically implanting the conductor.

1           3.     A method according to claim 2, wherein said surgically  
2     implanting step is further defined as thorascopically implanting the conductor.

1           4.     A method according to claim 1, wherein the implanted stimulus  
2     generator is selected from the group consisting of a pacemaker and a  
3     dcfibrillator.

1           5.     A method according to claim 1, wherein the conductor  
2     comprises an insulator disposed about at least a portion of the conductor.

1           6.     A method according to claim 1, wherein the conductor  
2     comprises a metallic wire.

1           7.     A method according to claim 1, wherein the conductor  
2     comprises a metallic strip.

1           8.     A method according to claim 1, wherein the conductor  
2     comprises a ribbon of conductive material.

1           9.     A method according to claim 1, wherein the conductor includes  
2     at least one electrical component disposed in electrical communication  
3     therewith.

1           10. A method according to claim 9, wherein the electrical  
2           component comprises a diode.

1           11. A method according to claim 9, wherein the electrical  
2           component comprises a device capable of storing energy.

1           12. A method according to claim 11, wherein the electrical  
2           component comprises a capacitor.

1           13. A method according to claim 9, wherein the electrical device  
2           comprises a resistor.

1           14. A method according to claim 9, wherein the electrical  
2           component comprises a microprocessor.

1           15. A passive conductor assembly for use with an implanted  
2           stimulus generator having an intracavitarily disposed stimulating lead for  
3           stimulating the heart of a subject, said conductor assembly comprising:

4           at least one conductive element having at least two electrically  
5           conductive contacts for contacting a portion of the heart of the subject.

WO 00/57950

PCT/US00/08695

21

1           16.    A conductor as set forth in claim 15, wherein said conductive  
2    element comprises an insulator disposed about at least a portion of said  
3    conductive element.

1           17.    A conductor as set forth in claim 15, wherein said conductive  
2    element comprises a metallic wire.

1           18.    A conductor as set forth in claim 15, wherein said conductive  
2    element comprises a metallic strip.

1           19.    A conductor as set forth in claim 15, wherein said conductive  
2    element comprises a ribbon of conductive material.

1           20.    A conductor as set forth in claim 15, wherein said conductive  
2    element includes at least one electrical component disposed in electrical  
3    communication therewith.

1           21.    A conductor as set forth in claim 20, wherein said electrical  
2    component comprises a diode.

1           22.    A conductor as set forth in claim 20, wherein said electrical  
2    component comprises a device capable of storing energy.

1           23.    A conductor as set forth in claim 22, wherein said electrical  
2    component comprises a capacitor.

1           24.    A conductor as set forth in claim 20, wherein said electrical  
2    component comprises a resistor.

1           25.    A conductor as set forth in claim 20, wherein said electrical  
2    component comprises a microprocessor.

1           26.    A method of neurally stimulating the heart of a subject, said  
2    method comprising the steps of:

3                disposing at least one conductor having at least two electrically  
4    conductive contacts adjacent to a portion of a heart in close proximity to an  
5    intracavitarily disposed electrode of an implanted stimulus generator;

6                contacting a portion of the heart with the electrically conductive  
7    contacts of the conductor;

8                positioning the electrically conductive contacts of the conductor in  
9    contact with myocardial tissue such that an electrical stimulus delivered by the  
10   implanted stimulus generator creates an electrical potential difference at each  
11   of the electrically conductive contacts of the conductor inducing the flow of  
12   current therethrough; and

13              generating an electrical stimulus from the implanted stimulus generator  
14   and discharging the electrical stimulus from the intracavitarily disposed



15 electrode wherein the stimulus is conducted through the myocardial tissue and  
16 through at least one electrically conductive contact and is conducted to the  
17 regions of the heart contacting other of the electrically conductive contacts of  
18 the conductor; and  
19 selectively stimulating neural tissue of the heart.

1 27. A method according to claim 26, wherein said inserting step  
2 further comprises surgically implanting the conductor.

1 28. A method according to claim 27, wherein said surgically  
2 implanting step is further defined as thorascopically implanting the conductor.

1 29. A method according to claim 26, wherein the implantable  
2 stimulus generator is selected from the group consisting of a pacemaker and a  
3 defibrillator.

1 30. A method according to claim 26, wherein the conductor  
2 comprises an insulator disposed about at least a portion of the conductor.

1 31. A method according to claim 26, wherein the conductor  
2 comprises a metallic wire.

1           32. A method according to claim 26, wherein the conductor  
2 comprises a metallic strip.

1           33. A method according to claim 26, wherein the conductor  
2 comprises a ribbon of conductive material.

1           34. A method according to claim 26, wherein the conductor  
2 includes at least one electrical component disposed in electrical communication  
3 therewith.

1           35. A method according to claim 34, wherein the electrical  
2 component comprises a diode.

1           36. A method according to claim 26, wherein the electrical  
2 component comprises a microprocessor.

1           37. A method according to claim 34, wherein the electrical  
2 component comprises a device capable of storing energy.

1           38. A method according to claim 37, wherein the electrical  
2 component comprises a capacitor.

1           39.     A method according to claim 34, wherein the electrical device  
2     comprises a resistor.

1           40.     A method according to claim 26, wherein said selectively  
2     stimulating step further includes modifying the electrical stimulus prior to  
3     contacting the heart whereby the stimulus substantially only stimulates neural  
4     tissue.

1           41.     A method for electrically stimulating a preselected area of a  
2     heart comprising the steps of:

3           attaching one end of an electric wire to a first area of the heart so that  
4     said one end of said wire is in electrical contact with said first area of the heart,  
5     and

6           attaching a second end of an electric wire to the preselected area of the  
7     heart so that said second end of said wire is in electrical contact with said first  
8     preselected area of the heart,

9           wherein said first and said preselected areas of the heart attain different  
10    electrical potential levels during cardiac contraction.

1           42.     The invention as defined in claim 41 wherein said wire includes  
2     electrical insulation between its ends.

1           43.    The invention as defined in claim 41 wherein each attaching  
2    step comprises the step of suturing said wire to the heart.

1           44.    The invention as defined in claim 41 and comprising the step of  
2    attaching at least one intermediate point of said wire to the heart so that said  
3    intermediate point of the wire is in electrical contact with the heart.

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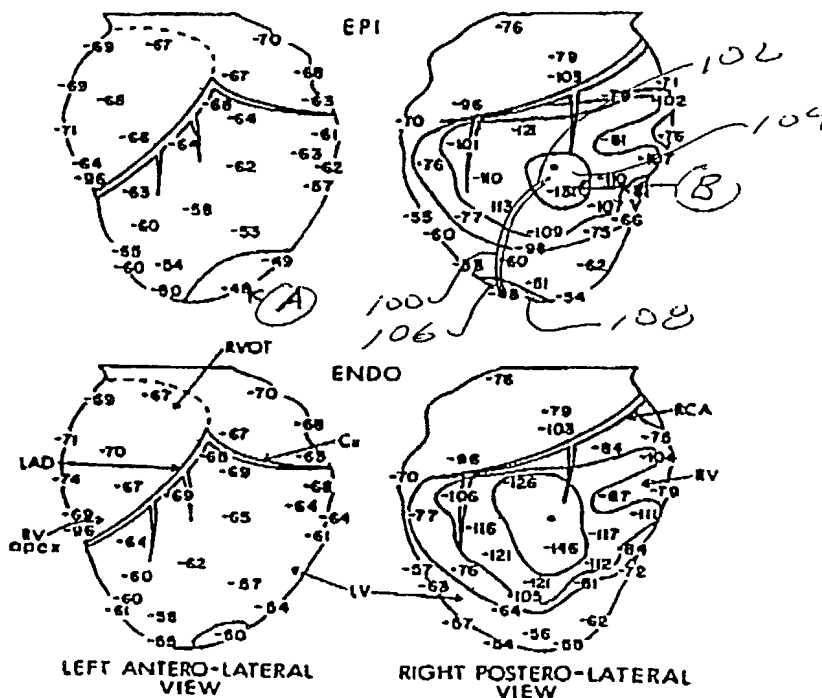
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(54) Title: METHOD AND APPARATUS FOR PASSIVE CARDIAC STIMULATION

(57) Abstract

This invention is a passive conductor assembly for use with an implanted device having an intra-cavitarily or trans-venously disposed electrode. The assembly can include electrical components in electrical communication therewith which provide for the manipulation, and/or modification of the electrical stimulus or waveform generated by the implanted stimulus generator, which can be designed, for example, to selectively stimulate only neural tissue, not cardiac tissue or vice versa through the same passive conductor assembly.

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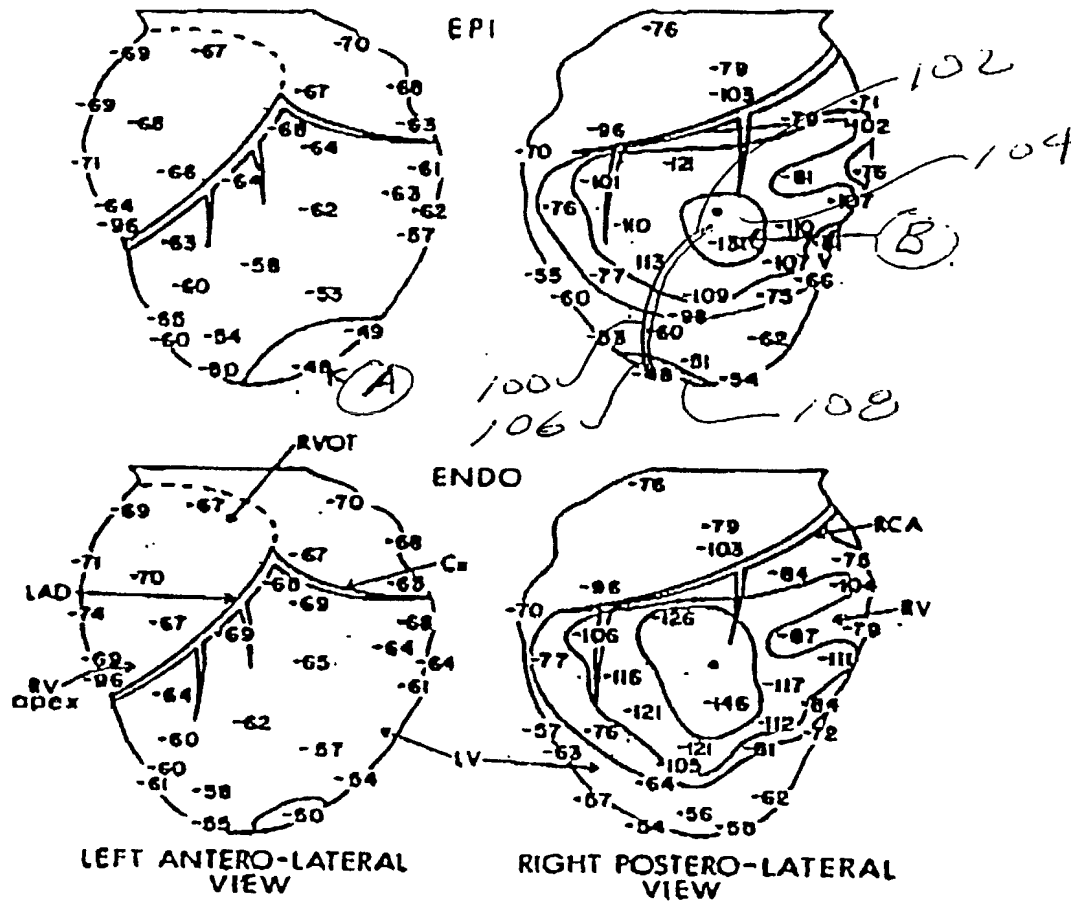


FIGURE 1

Docket No.  
UAB-15602/22

## Declaration and Power of Attorney For Patent Application

### English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

#### METHOD AND APPARATUS FOR PASSIVE CARDIAC STIMULATION

the specification of which

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☐ is attached hereto.

☒ was filed on 30 March 2000 as United States Application No. or PCT International Application Number PCT/US00/08695 and was amended on \_\_\_\_\_

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I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

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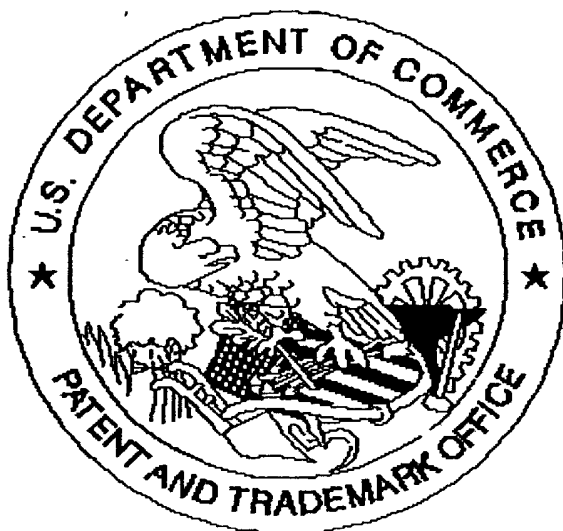
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